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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,782	05/27/2004	Douglas Ray Sparks	IFP-24	3781

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EXAMINER	
HUH, BENJAMIN	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/709,782	SPARKS ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 39-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 39-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I which is claims 1-12 and 39-58 in the reply filed on 10/05/06 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 7, 39, 41, 60, 62-63, 66, & 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Steil et al (US Pub. No. 2004/0193025 A1). The Steil reference discloses a device and method for detecting a chemical or biological agent and treating a person if the person is exposed to the agent in figures 1-39b, the device comprising a small and lightweight unit comprising at least one antidote 24, means for selecting the antidote 12, means for delivering 14 the antidote, means for communication between the selecting means and the delivering means 12 as well, means for detecting 10. Wherein glucose is seen to be the biological or chemical agent and insulin the antidote. With respect to the method, wherein it is seen that the device can send a signal to the

selecting means whether or not if the agent is detected, for example a continuous signal.

Claims 1, 3-5, 7, 12, 39, 41-43, 45, 50-51, 53, 58-60, 62, 63-65, & 69-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Schetky et al (US Pub. 2004/0158232 A1). The Schetky reference discloses a device and method for detecting a chemical or biological agent and treating a person if the person is exposed to the agent in figures 1-8, the device comprising a small and lightweight unit comprising at least one antidote, see para [0018], means for selecting the antidote 36 also see figure 8, means for delivering 20A/20B the antidote, means for communication between the selecting means and the delivering means 36 as well see figure 8, means for detecting, seen as the blood glucose sensor or other sensors. Wherein glucose is seen to be the biological or chemical agent and insulin the antidote. With respect to the method, wherein it is seen that the device can send a signal to the selecting means whether or not if the agent is detected, for example a continuous signal.

Claims 1, 3-7, 39, 41-45, 47-55, 58-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Currie et al (US Patent No. 6887202 B2). The Currie reference discloses a device and method for detecting a chemical or biological agent and treating a person if the person is exposed to the agent, the device comprising a unit small and lightweight comprising at least one antidote, means for delivering the antidote, means for communication between the selecting means and the delivering means, means for

detecting the presence of at least one agent in a fluid sample near the person, the detecting means being in communication with the selecting means and operable to detect the fluid sample, identify the at least one antidote and then delivering the antidote, see abstract, col. 1 lines 16 – 60, col. 3 lines 2- col. 4 line 5, col.5 line 10 – col. 6 line 34, col. 6 line 47 – col. 7 line 47, col. 13 line 47 – col. 16 line 31, col. 30 line 22- col. 47 line 37.

With respect to claims 60-63 & 66-69, see col. 6 line 35 – col. 7 line 47 & col. 32 line 40 – 56.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 6, 9, 11, 40, 44, 47-49, 52, 54-55, & 57 are rejected under 35 U.S.C. 103(a) as being obvious over Steil et al (US Pub. No. 2004/0193025 A1) or Schetky et al (US Pub. 2004/0158232 A1) as applied to claims 1 or 39 and further in view of Sparks (US Patent No. 6932114B2). Now even though Steil or Schetky do not explicitly disclose a tube comprising a freestanding tube portion, means for vibrating the tube at a resonant frequency utilizing the Coriolis effect, means for sensing the movement of the freestanding tube, means for measuring the elapsed time, and means for stopping the flow attention is directed to Sparks. The Sparks reference teaches a fluid delivery

system utilizing a freestanding tube in order to provide a system which delivers a precise amount of fluid and monitors property of the fluid. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Schetky or Steil to incorporate the fluid delivery system of Sparks in order to provide a precise delivery and monitoring system to improve delivery accuracy.

With respect to claims 6, 44, 49, 52, 54-55, 57, wherein it would be obvious to one of ordinary skill in the art to also perform the detecting and identifying remote from the person such as in a sterile environment and through other methods such as urine or blood analysis out of the body.

With respect to claims 11 & 57, wherein the alert signal is not fully defined and is seen to be any signal sent to a location when the fluid commences, therefore the signal could be that of a controller telling the pump to commence which moves the fluid.

With respect to claim 47, wherein it would be obvious to one of ordinary skill in the art to insert the delivering means into the body, such as a needle or catheter for injection purposes, after the detecting and identifying has been performed in order to prevent the need to insert the patient with a needle or catheter.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject

matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 10 & 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steil et al (US Pub. No. 2004/0193025 A1) or Schetky et al (US Pub. 2004/0158232 A1) as applied to claims 1 or 39 and further in view of Arzbaecher et al (US Pub. No. 2003/0191402A1). Now even though Steil or Schetky do not explicitly disclose sending a signal indicating the location of the person attention is directed to Arzbaecher. The Arzbaecher reference teaches the use of a medical device which can transmit an alarm and a signal indicating the location of the person when there is a detected problem of the person's biological conditions. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Steil or Schetky to incorporate the teachings of Arzbaecher in order to provide a safety mechanism to the patient as well as to notify medical authorities of a problem so that help can be dispatched.

Allowable Subject Matter

Claims 8 & 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and the specification objection were to be overcome.

Response to Arguments

Applicant's arguments filed 3/24/07 have been fully considered but they are not persuasive.

The examiner would also like to note that the specification objection has been withdrawn and thanks the applicant for responding to the objection accordingly with the locations within the specification of support for the 112 6th paragraph in the claims.

Applicant argues that Steil nor Schetky operate if the person is exposed to glucose and only deliver if glucose is detected, the examiner would like to note that this point is moot. The claims do not explicitly state that the device works ONLY if the person is exposed. With the example of glucose, the person meets the condition for the device to work since the person IS exposed to glucose, as there is glucose constantly in the body. The amount of glucose in the body does determine though the amount if at all any insulin is delivered to the body.

Applicant argues that the reference do not "identify" or select" the insulin, the examiner disagrees. The term "identify" or "select" is extremely broad and it is the examiner's position that since the insulin is delivered in response to the sensed level of

glucose, the insulin is "selected" to be delivered. Also, just because there is only one option does not mean that the option is not selected if taken. For example, if a driver only has one car to choose from to drive, the driver can still "select" to drive that one car.

Applicant argues that Steil and Schetky fail to disclose the subject matter of claims 4-5, the examiner would like to note that this point is moot in view of Steil and the examiner disagrees in view of Schetky. With respect to Steil, the reference does not utilize the 102 rejection to encompass claims 4-5. With respect to Schetky, the schetky reference discloses the use of insulin and an anti-inflammatory.

Applicant argues that it is IMPOSSIBLE to remotely sense glucose in a person, the examiner disagrees. Due to the broad wording of the claims, the examiner would like to point out that glucose monitors that are remote from the person are well known in the art. Prior to having a glucose monitor attached to the person, person with diabetes had to utilize a glucose monitor that analyzed a portion of blood to sense remotely the glucose in the person to help in identifying the amount of insulin needed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

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SUPERVISORY PRIMARY EXAMINER